

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CASE NO. 8:03-cv-2627-T-24TBM

PHARMAKON LABORATORY, INC., a
Corporation; and ABELARDO L.
ACEBO and EDWARD R. JACKSON,
individuals,

Defendants.

_____ /

AMENDED COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by and through Paul I. Perez, the United States Attorney for the Middle District of Florida, alleges as follows:

1. Plaintiff brings this statutory injunction action under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), to enjoin defendants Pharmakon Laboratory, Inc. ("Pharmakon"), a corporation, Abelardo L. Acebo, President of Pharmakon, an individual, and Edward R. Jackson, Secretary/Treasurer of Pharmakon, an individual (collectively, "defendants"), from (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered,

into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353 (b)(4)(B); (d) violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); and (e) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

4. Defendant Pharmakon is incorporated under the laws of the State of Florida, and does business at 6119 and 6050 Jet Port Industrial Boulevard, Tampa, Florida, within the jurisdiction of this Court. Pharmakon is engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing over-the-counter and prescription drugs in both liquid and tablet form.

5. Defendant Abelardo L. Acebo, an individual, is the President and co-owner of Pharmakon. He has authority over, and responsibility for, all operations of Pharmakon, including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of drugs. He performs his duties at 6050 and 6119 Jet Port Industrial Boulevard, Tampa, Florida, within the jurisdiction of this Court.

6. Defendant Edward R. Jackson, an individual, is the Secretary/Treasurer, co-owner, and Quality Control Director of Pharmakon. He shares responsibility with Defendant Acebo for all management decisions related to Pharmakon's manufacture,

processing, packing, labeling, holding, and distribution of drugs. He performs his duties at 6050 and 6119 Jet Port Industrial Boulevard, Tampa, Florida, within the jurisdiction of this Court.

7. Defendants purchase components used to manufacture their drugs in interstate commerce from firms located outside of Florida, including firms in New Jersey, California, Texas, and Illinois. Defendants ship a majority of their finished drugs in interstate commerce to companies in Puerto Rico.

8. Defendants have been and are now engaged at their plants at 6050 and 6119 Jet Port Industrial Boulevard, Tampa, Florida, in manufacturing, processing, packing, holding, and distributing in interstate commerce various products that are drugs within the meaning of 21 U.S.C. § 321(g)(1) in that they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" in humans.

9. FDA has established and published monographs that identify certain categories of drugs that can be marketed as OTC drugs, provided they comply with specific regulatory criteria. 21 C.F.R. Part 330. Drugs marketed in conformance with these OTC monographs are generally recognized as safe and effective, 21 C.F.R. § 330.1, and can be marketed without the submission and approval of new drug applications ("NDAs").

10. Defendants manufacture, process, pack, label, hold, and distribute several OTC drug products subject to FDA monographs, including the monograph governing "Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over the Counter Use," 21 C.F.R. Part 341 (hereinafter, the "Cough/Cold Monograph").

Adulteration

11. The United States Food and Drug Administration's ("FDA") inspections of defendants' facilities have established that the drugs manufactured and distributed by defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) because the methods used in, and the facilities and controls used for, their manufacture, processing, packing, holding, and distribution fail to conform with FDA regulations establishing current good manufacturing practice ("CGMP"). See 21 C.F.R. §§ 210, 211.

12. CGMP includes procedures and practices that are intended to ensure that drugs have the quality, purity, and other attributes necessary for their safe and effective use. FDA regulations, which establish minimum CGMP requirements applicable to human drugs, 21 C.F.R. §§ 210, 211, require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured to prevent production of unsafe and ineffective products. Drugs not made in conformance with CGMP are "adulterated" as a matter of law. 21 U.S.C. § 351(a)(2)(B).

13. FDA most recently inspected defendants' facility from October 9 to November 12, 2002. This inspection was conducted as a follow-up to twenty-five complaints that alleged adverse reactions to Genexotic Hydrocortisone ("HC") ear drops ("Genexotic"), a generic form of Exotic HC manufactured by defendants and indicated to treat superficial infections, inflammation, or itching of the external auditory canal. The complaints were submitted through MedWatch, the FDA safety information and adverse event reporting program. Among other things, MedWatch allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs they prescribe, dispense, or use. The complaints related to

Genexotic included reddening of the external auditory canal that often required emergency room visits, hospitalization, and, in one case, surgery.

14. The October to November 2002 inspection revealed that the methods used in, and the facilities and controls used for, the manufacture, packing, processing, labeling, holding, and distribution of defendants' drugs are not in compliance with drug CGMP. These drugs, therefore, are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

15. During the inspection, FDA investigators documented many deviations from CGMP related to personnel, equipment, control of drug product components, production and process controls, packaging and labeling controls, laboratory controls, and records and reports. The most significant deviations included, but were not limited to, the following:

A. Drug components were not appropriately tested for identity, quality, or suitability, see 21 C.F.R. § 211.84;

B. Scientifically meaningful sample plans had not been established to assess product quality, and laboratory testing is not appropriate, as evidenced by Pharmakon's failure to establish the reliability of test results received from outside laboratories and reliance on outside laboratory test results despite disclaimers from the laboratory that testing methods were not validated, see 21 C.F.R. § 211.165;

C. Written procedures for monitoring manufacturing processes to ensure that they consistently produce drugs of acceptable quality were insufficient or had not been implemented, see 21 C.F.R. § 211.100(a);

D. The written stability testing program omitted certain necessary information, including, but not limited to, reliable, meaningful, and specific test methods that are stability indicating, see 21 C.F.R. § 211.166(a);

E. Master production and control records were not prepared for each drug product, there was no written procedure for preparing these records, and batch component lists did not use uniform units of measurement, see 21 C.F.R. § 211.186;

F. Batch records did not contain all information required by the regulations, including, but not limited to, weights and measures actually used in processing and results of in-process controls, see 21 C.F.R. § 211.188(b);

G. Equipment cleaning and maintenance procedures had not been validated, residue limits had not been established, and test methods had not been validated, see 21 C.F.R. § 211.67(a) & (b);

H. Written procedures for verifying label quality and content accuracy did not address product-package inserts and did not provide instructions for representative sampling, see 21 C.F.R. § 211.122(a);

I. Employees and supervisors, including those working in quality control, were not adequately trained in CGMP and other areas relevant to their assigned functions and responsibilities, see 21 C.F.R. § 211.25(a) & (b); and

J. The testing laboratory used by the quality control unit was inadequate, see 21 C.F.R. § 211.22(b).

16. Previous inspections of Pharmakon have combined to establish a consistent history of failure to comply with CGMP. Inspections conducted by FDA from June 6 to 13, 2001, January 23 to March 11, 2002, and May 7 to 20, 2002, revealed

deviations from CGMP that were substantially similar to, and equally serious as, the non-compliant practices observed and documented in the most recent inspection described above.

Misbranding

17. While reviewing the defendants' documents, including batch records and product labels of recently manufactured products, produced pursuant to the government's Requests for Production of Documents served on April 1, 2004, Compliance Officers at FDA's Center for Drug Evaluation and Research ("CDER") discovered that several drug products were labeled with the "Rx" symbol, despite the fact that these drugs are not prescription drugs. Pursuant to 21 U.S.C. § 353(b)(4)(B), non-prescription drug products that bear the Rx symbol are deemed misbranded.

18. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

19. Defendants violate 21 U.S.C. § 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

Unapproved New Drugs

20. The CDER Compliance Officers' review of defendants' documents produced pursuant to the government's discovery requests also revealed that several drug products produced by Pharmakon are unapproved new drugs as follows:

A. Defendants' GeneBronco-D liquid drug products contain a lower dosage of a particular ingredient, pseudoephedrine Hcl, than is permitted in the

Cough/Cold Monograph, 21 C.F.R. § 341.80(d)(1)(ii). This deviation from the monograph causes these drug products to be unapproved new drugs under the Act because they are not generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling, and they are being marketed by Pharmakon without FDA approval under 21 U.S.C. § 355.

B. Defendants' drug product Defensol-D Tablets contain a lower dosage of a particular ingredient, chlorpheniramine maleate, than is permitted in the Cough/Cold Monograph, 21 C.F.R. § 341.74(d)(3). This deviation from the monograph causes these drug products to be unapproved new drugs under the Act because they are not generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling, and they are being marketed by Pharmakon without FDA approval under 21 U.S.C. § 355.

C. Several of defendants' drug products are timed release dosage forms, which are new drugs under 21 C.F.R. § 310.502(a)(14). These drug products are unapproved because they are being marketed by Pharmakon without FDA approval under 21 U.S.C. § 355.

D. Several of defendants' drug products contain active ingredients that are related or similar to drug products found to be effective under the "Drug Efficacy Study Implementation" ("DESI"). As products similar or related to DESI-reviewed drugs, the defendants' drug products containing hydrocodone bitartrate require approved drug applications prior to commercial distribution. 21 C.F.R. § 310.6. These drug products are unapproved new drugs under the Act because they not generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling,

and they are being marketed by Pharmakon without FDA approval under 21 U.S.C. § 355.

E. Several of defendants' drug products contain active ingredients that are unapproved new drug products because they are not generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling, and they are being marketed by Pharmakon without FDA approval under 21 U.S.C. § 355.

21. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

History of Violations

22. Defendants have received numerous warnings about their violative conduct. At the close of each inspection, including the most recent one ending in November 2002, FDA investigators issued to defendants a detailed List of Inspectional Observations ("Form FDA-483"), which notified them of the investigators' observations. The FDA investigators also discussed with defendants the violations listed in the Form FDA-483, and defendants promised to correct the CGMP deviations during these discussions.

23. Defendants have long been aware of the nature and gravity of the unlawful deficiencies in their operations. Following the first inspection, FDA issued a Warning Letter to defendants on September 7, 2001. This Warning Letter emphasized the serious nature of defendants' CGMP deviations and alerted defendants that further regulatory action could result if they did not correct these deviations. Defendants

requested a meeting with FDA in order to address the issues raised in the Warning Letter. During this meeting, which was held on October 4, 2001, defendants promised to correct all of the deviations observed by FDA.

24. Despite the numerous written warnings and promises of corrections, defendants continue to violate the law. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

25. Defendants also violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

26. Defendants' history of CGMP deviations demonstrates their unwillingness and/or inability to come into compliance with the Act and the CGMP regulations. FDA has warned defendants that their CGMP deviations could subject them to regulatory action, and FDA officials repeatedly have discussed with defendants their CGMP deviations. Notwithstanding these warnings and assurances from defendants that the CGMP deviations had been, or would be, remedied, defendants have failed to come into compliance with the CGMP regulations and the violations of the Act continue.

27. Based upon their repeated course of conduct, defendants, unless restrained by order of this Court, will continue to process and distribute adulterated drugs in violation of the Act, 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff prays:

I. That defendants Pharmakon Laboratory, Inc., a corporation, and Abelardo L. Acebo and Edward R. Jackson, individuals, and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, be preliminarily and perpetually restrained and enjoined from any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any article of drug that is adulterated; and

B. Violating 21 U.S.C. § 331(k) by adulterating any article of drug while such article is being held for sale after one or more of the components of such drug have been shipped in interstate commerce.

C. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of § 353(b)(4)(B);

D. Violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); and

E. Violating 21 U.S.C. 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

II. That defendants Pharmakon Laboratory, Inc., a corporation, and Abelardo L. Acebo and Edward R. Jackson, individuals, and each and all of their directors,

officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, be preliminarily and perpetually restrained and enjoined from directly or indirectly introducing or causing the introduction into interstate commerce of any drug, or holding for sale any drug after shipment of one or more of its components in interstate commerce, unless and until defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, or distribute articles of drug are established, operated, and administered in conformity with CGMP, and in a manner that has been found acceptable to FDA; and

III. That the Court award plaintiff costs and other such relief as the Court deems just and proper.

DATED this _____ day of _____, 2004.

Respectfully submitted,

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